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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,520	01/17/2002	James E. Rothman	11746/46004	3143

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JONES DAY
222 EAST 41ST ST
NEW YORK, NY 10017

EXAMINER	
BASI, NIRMAL SINGH	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 04/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/053,520	ROTHMAN ET AL.	
	Examiner	Art Unit	
	Nirmal S. Basi	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18,28,31,33 and 35-99* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *18,28,31,33 and 35-99* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/12/03, 12/29/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Amendments filed 12/29/05 has been entered. IDS filed 12/29/05 has been considered. IDS filed 5/12/03 has not been considered because the references were not provided.

2. Upon further review the claims have been restricted as shown below.

3. **Election/Restriction**

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 18, 31, 33, 35, 41, 43, 45, 48, 50-75, 76-89 drawn to a method of inducing an immune response in a subject in need thereof comprising administering to the subject, a composition comprising a conjugate peptide, wherein the conjugate peptide comprises (i) a first portion which binds to a heat shock protein under physiologic conditions, and (ii) a second portion which comprises an antigenic peptide of a neoplasia, wherein a heat shock protein is not concurrently administered with the conjugate peptide, whereby an immune response to said second portion is induced in said subject, said immune response being to an antigen of said neoplasia., classified in class 424, subclass 185.1, for example .

II. Claims 18, 31, 33, 35, 41, 43, 45, 48, 50-75, 76-89 drawn to a method of inducing an immune response in a subject in need thereof comprising

administering to the subject, a composition comprising a conjugate peptide, wherein the conjugate peptide comprises (i) a first portion which binds to a heat shock protein under physiologic conditions, and (ii) a second portion which comprises an antigenic peptide of a pathogen, wherein a heat shock protein is not concurrently administered with the conjugate peptide, whereby an immune response to said second portion is induced in said subject, said immune response being to an antigen of said pathogen, classified in class 424, subclass 185.1, for example .

III. Claims 28, 36-40, 42, 44, 46, 47, 49, 72-75, 86, 87, 90-99, drawn to method of inducing an immune response in a subject in need thereof, comprising administering, to the subject a composition comprising a conjugate peptide, wherein the conjugate peptide comprises (i) a benzoquinone ansamycin antibiotic, and (ii) an antigenic peptide, whereby an immune response to said antigenic peptide is induced in said subject, classified in class 424, subclass 1.65, for example .

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim--, drawn to --, classified in class --, subclass --.

II. Claim--, drawn to --, classified in class --, subclass --.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I-III are directed to inducing an immune response in a subject. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the method of group I induces an immune response using conjugate peptide, wherein the conjugate peptide comprises (i) a first portion peptide which binds to a heat shock protein under physiologic conditions, and (ii) a second portion which comprises an antigenic peptide of a neoplasia, said immune response being to an antigen of said neoplasia.

3. The method of group I induces an immune response using conjugate peptide, wherein the conjugate peptide comprises (i) a first portion peptide which binds to a heat shock protein under physiologic conditions, and (ii) a second portion which comprises an antigenic peptide of a pathogen, said immune response being to an antigen of said pathogen. The method of group III induces an immune response conjugate peptide comprises (i) a benzoquinone ansamycin antibiotic, and (ii) an antigenic peptide. The methods are patatenably distinct because they use different compounds to produce immune responses to different antigens. Further the immune response produced need not be the same in all three cases.

The methods of Inventions I-III are distinct because they are independent, using separate method steps, active agents and may produce different immune responses. The methods of Inventions I and II are distinct because they

produce immune responses to two distinct types of pathologically different diseases with different etiologies, modes of action with no common antigen.

A search of the art for Inventions I-III would not be co-extensive with each other. Because the searches required for these inventions are not co-extensive an examination of the materially different, patentably distinct inventions in a single application would constitute a serious burden on the examiner. The inventions have a separate status in the art as shown by their different classifications.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

4. This application contains claims directed to the following patentably distinct species:

Species I.

Any one of the heat shock proteins disclosed specification binding

Species II.

Benzoquinone ansamycin selected from geldanamycin, herbimycin A, mimosamycin, macmimycin 1 and kuwaitimycin.

Species III.

A neoplasia selected from the group consisting of sarcoma, lymphoma, leukemia, melanoma, carcinoma of the breast, carcinoma of the prostate, ovarian carcinoma, carcinoma of the cervix, uterine carcinoma, colon carcinoma, carcinoma of the lung, glioblastoma, and astrocytoma;

Species IV.

The pathogen selected from the group consisting of a bacterium, a virus, a protozoan, a mycoplasma, a fungus, a yeast, a parasite, and a prion.

Species V.

The bacterium selected from *Salmonella, Staphylococcus, Streptococcus, Enterococcus, Clostridium, Escherichiq Klebsiella, Vibrio, Mycobacterium, and Mycoplasma pneumoniae.*

Species VI.

The virus selected from human papilloma virus, herpes virus, retrovirus, hepatitis virus, influenza virus, rhinovirus, respiratory syncytial virus, cytomegalovirus, adenovirus, herpes simplex virus, herpes zoster virus, human immunodeficiency 1, and human immunodeficiency 2

Species VII.

The protozoan selected from amoeba, a malarial parasite, or *Trpanosoma cruzi.*

The species are independent or distinct because they are drawn to entirely different compounds which have different structures, biological properties, activities and modes of action. Further all the diseases have different etiologies, modes of action with no common antigen.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 18, 28, 31 and 88. generic.

It is noted that different heat shock proteins recited in the specification that produce an immune response are patentably distinct, because they are structurally and functionally different compounds capable of separate use and manufacture. Thus the generic linking claims 18, 31 are improper.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal S. Basi whose telephone number is 571-272-0868. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax

phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nirmal S. Basi
Art unit 1646
4/17/06

JANET L. ANDRES
SUPERVISORY PATENT EXAMINER